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Re-evaluation Decision RVD2011-10

Formaldehyde and Paraformaldehyde

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Table of Contents

Re-evaluation Decision for Formaldehyde and Paraformaldehyde 1
What Does Health Canada Consider When Making a Re-evaluation Decision? 1
What Is Formaldehyde and Paraformaldehyde? 2
Health Considerations 2
Environmental Considerations 3
Measures to Minimize Risk 3
What Additional Scientific Information Is Required? 3
Other Information 4
Appendix I Data Required as a Condition for Continued Registration for Formaldehyde 5
Appendix II Comments and Responses 7
Appendix III Label Amendments for Products Containing Formaldehyde 11
Appendix IV Label Amendments for Products Containing Paraformaldehyde 15

Re-evaluation Decision for Formaldehyde and Paraformaldehyde

After a re-evaluation of the antimicrobials formaldehyde and paraformaldehyde, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing formaldehyde and paraformaldehyde for sale and use in Canada.

An evaluation of available scientific information found that products containing formaldehyde and paraformaldehyde do not present unacceptable risks to human health or the environment when used according to revised label directions. As a condition of the continued registration of formaldehyde and paraformaldehyde uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation (Appendix I).

The regulatory approach for the re-evaluation of formaldehyde and paraformaldehyde was first presented in the consultation document[1] Proposed Re-evaluation Decision PRVD2010-10, *Formaldehyde and Paraformaldehyde*. This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of formaldehyde and paraformaldehyde as well as summarizes the Agency's decision and the reasons for it. Appendix II summarizes comments and information received during the consultation process and the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-10. Label amendment wording and format has been revised. To comply with this decision, registrants of products containing formaldehyde and paraformaldehyde will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Formaldehyde and paraformaldehyde have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of formaldehyde and paraformaldehyde. In this decision, the PMRA took into account the Canadian use pattern and issues (such as the federal Toxic Substances Management Policy).

The USEPA re-evaluated formaldehyde and paraformaldehyde and published its conclusions in a 2008 RED. The PMRA is aware that the USEPA assessment of formaldehyde is ongoing. The PMRA may re-assess formaldehyde and paraformaldehyde in the future, as required.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-10, *Formaldehyde and Paraformaldehyde*.

What Is Formaldehyde and Paraformaldehyde?

Formaldehyde is an antimicrobial pesticide that is used in mushroom production, agricultural buildings, for seed treatment, and in bulb production. Formaldehyde is applied using fumigation, spray, dip or cloth/mop.

Paraformaldehyde (a polymer of formaldehyde) is an antimicrobial agent that is used in alfalfa leafcutting bee (*Megachile rotundata*) production. Paraformaldehyde is applied by fumigation.

Health Considerations

Can Approved Uses of Formaldehyde and Paraformaldehyde Affect Human Health?

Formaldehyde and paraformaldehyde are unlikely to affect your health when used according to the revised label directions.

People could be exposed to formaldehyde and paraformaldehyde when working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that formaldehyde and paraformaldehyde were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Formaldehyde and Paraformaldehyde Are Introduced Into the Environment?

Formaldehyde and paraformaldehyde are unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that uses of formaldehyde and paraformaldehyde were unlikely to affect non-target organisms provided that additional advisory statements to further protect the environment were implemented. These conclusions apply to the Canadian situation.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of formaldehyde and paraformaldehyde, the PMRA is requiring further risk-reduction measures for product labels (Appendix III and IV).

Human Health

- Additional directions for use label statements.
- Removal of application using a broom.
- Additional precautionary label statement including revised personal protective equipment for handlers.
- Reduced application rates for mushroom house cleanout and general disinfection uses.
- Ventilation requirements prior to re-entry by unprotected persons.
- Certification requirements for handlers applying formaldehyde or paraformaldehyde by fumigation.
- Posting requirements for all uses.

Environment

- Additional directions for use label statements

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of the formaldehyde active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter that will be sent. Appendix I lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on formaldehyde and paraformaldehyde within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Data Required as a Condition for Continued Registration for Formaldehyde

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrant of formaldehyde is required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to registrants of the technical active ingredients by the PMRA.

DACO 2	The entire Part 2 chemistry data for the formaldehyde technical product are required. This study must be conducted with the relevant technical grade active ingredient.
DACO 10.2.3.2	Laboratory Trials: The new lower formaldehyde rate of 0.19 g a.i./L must be tested to ensure it is effective. Testing may be carried out using protocols derived from EPA DIS-TSS 01 (Disinfectants for Use on Hard Surfaces), or DIS-TSS 10 (Sanitizer Test for Inanimate Surfaces), or ASTM E-2192-02 (Standard Quantitative Disk Carrier Test Method for Determining the Bactericidal, Virucidal, Fungicidal, Mycobactericidal and Sporocidal Activities of Liquid Chemical Germicide). The microorganisms being used in the tests must be relevant to the use pattern (for example, mushroom pathogens for mushroom houses disinfection).

Appendix II Comments and Responses

The PMRA received comments relating to the Proposed Re-evaluation Decision PRVD2010-10, *Formaldehyde and Paraformaldehyde*. The comments have been summarized, and the corresponding responses are presented below.

1. The use of formaldehyde for bulb dip

Comment:
The proposed label amendments outlined in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, are unclear if control of nematodes on ornamental bulbs is supported for continued registration and if a pesticide applicator certificate would be required for these handlers.

PMRA Response:
The use of formaldehyde for ornamental bulbs is eligible for continued registration provided the revised risk reduction measures are adopted. The wording of the label statements has been revised for clarity. Handlers using formaldehyde for bulb dipping do not require a pesticide applicator certificate unless this is required by the provincial/territorial pesticide regulatory agency. Only handlers applying formaldehyde and paraformaldehyde by fumigation require an applicator certificate.

2. Phase out of certain mushroom production uses

Comment:
The uses of formaldehyde on casing soil and at mushroom composting facilities which are proposed for phase-out in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, are critical uses and should be maintained.

PMRA Response:
Following the re-evaluation announcement for formaldehyde, the registrant of the Canadian product indicated that they intended to provide continued support for only certain uses. Formaldehyde use on mushroom casing soil and mushroom composting yards and concrete slabs are no longer supported by the registrant and will be removed from the product label.

3. The use of formaldehyde in mushroom production.

Comment:
The proposed label statement in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, which limits application to indoor non-producing areas, would preclude the use of formaldehyde in mushroom growing rooms.

PMRA Response:
The proposed label statement in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, which limits application to "indoor non-producing areas" represents areas of a mushroom house that are not currently in active production. Application inside the mushroom growing room is permitted provided no mushrooms are present at the time of application. For clarity, the label statement has been revised to *"Application is limited to empty mushroom houses that are free of all mushrooms, persons, growing media, equipment and debris"*.

Comment:
Due to the layout of the buildings and growing rooms, mushroom farms cannot comply with the proposed label statement in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, which calls for an eight meter prohibited entry zone surrounding buildings being fumigated. Equivalent risk mitigation would be achieved by requiring growing room be sealed and locked with posted notification and ventilation requirements before re-entry.

PMRA Response:
The required label amendments have been organized based on individual uses for improved clarity. An eight meter prohibited entry zone requirement only applies to uses where the product is applied by fumigation.

Comment:
The proposed label statement in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, which prohibits formaldehyde use on surfaces that may have either direct or indirect contact with food or feed could be misleading to growers as the mushroom bed structures are in the rooms being treated. It is recommended that the label statement wording be revised to *"Do not apply formaldehyde onto surfaces that come in contact with food or feed"*. The proposed label statement in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, which requires the use of soap or detergent to wash surfaces prior to use of formaldehyde, will be difficult for growers as use of soap and detergent is not always feasible. Revised label wording requiring surfaces be washed with water instead of soap or detergent is recommended.

PMRA Response:
The PMRA accepts the recommended label revisions. The label statement has been revised to *"All surfaces should be washed prior to use of formaldehyde. DO NOT apply formaldehyde to surfaces that may come in contact with food. Surfaces that might come in contact with animal feed or water should be washed with soap or detergent post application."*

4. The use of paraformaldehyde in alfalfa leafcutting bee production

Comment:
The proposed requirement in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, requiring an applicator's certificate for paraformaldehyde fumigation of alfalfa leaf-cutting bee cells and nest material is unjustified given the history of safe use and experienced alfalfa growers in Canada.

PMRA Response:
An applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the application is to occur is required for all formaldehyde and paraformaldehyde fumigation uses to educate handlers with safe fumigation practices.

Comment:
The reference to a hatching incubator in PRVD2010-10, *Formaldehyde and Paraformaldehyde*, is incorrect in this context. It is recommended that the word hatching be removed for clarity.

PMRA Response:
The PMRA accepts the recommended label revision. The label statement has been revised to *"After transfer of bee cells to the incubator, ventilation of the incubator must continue for 5-7 days to capture residual formaldehyde vapour."*

Appendix III Label Amendments for Products Containing Formaldehyde

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following uses are not eligible for continued registration and must be removed from end-use product labels:

Mushroom casing soil, diseased areas on mushroom beds, mushroom composting yards and concrete slabs, potato diseases, smuts in grain, sanitization of tools and equipment used for bulb production.

Manual application of formaldehyde using a broom.

II) The end-use product labels must be amended to indicate a maximum application rate

Mushroom house cleanout: 0.19 g a.i./L.

General disinfection: 0.19 g a.i./L.

III) The following statements must be included on the primary display panel.

DANGER POISON

DANGER – CORROSIVE TO EYES

DANGER SKIN IRRITANT

POTENTIAL SKIN SENSITIZER

The following statements must be included on the secondary display panel.

Fatal or Poisonous if swallowed.
Extremely hazardous by skin contact. DO NOT get on skin.
CORROSIVE to the eye. DO NOT get in eyes.
CORROSIVE to the skin. DO NOT get on skin.
Potential skin sensitizer

IV) The following statements must be included in a section entitled **PRECAUTIONS**

All handlers must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and footwear, chemical-resistant headgear (during overhead application) and a full face respirator. During cleaning of equipment or mixing/loading product a chemical-resistant apron must also be worn.

V) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

For all formaldehyde uses:

An appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur is required for all fumigation uses. The provincial/territorial pesticide regulatory agency may also require a pesticide applicator certificate or licence for other uses.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

All surfaces should be washed prior to use of formaldehyde. DO NOT apply formaldehyde to surfaces that may come in contact with food. Surfaces that might come in contact with animal feed or water should be washed with soap or detergent post application.

Warning signs must be posted on, or in the vicinity, of all entrances. Signs must state "DANGER – FORMALDEHYDE" with skull and crossbones symbol, date and time of application, and contact information of applicator. Signs may not be removed until ventilation is complete and the premise is safe for re-entry.

Ventilation must achieve a total of 12 air-changes prior to re-entry by unprotected persons.

For Mushroom House Cleanout use:

Application is limited to empty mushroom houses that are free of all mushrooms, persons, growing media, equipment, debris, etc.

Mushroom houses must be securely locked until ventilation is complete and the mushroom house is safe for re-entry.

For General Disinfection use:

Application is limited to indoor areas that are free of all persons, animals, soil, produce, equipment, debris, etc.

For Poultry House Fumigation use:

Application is limited to empty poultry houses that are free of all persons, animals, soil, produce, equipment, debris, etc.

Poultry houses must be securely locked during fumigation and until ventilation is complete and the house is safe for re-entry.

An eight meter prohibited entry zone must be established extending from, and surrounding, the building being fumigated. Prohibited entry zone must be clearly identified with cones and cautionary tape. No persons except for properly equipped handlers are permitted within the prohibited entry zone. The prohibited entry zone must remain until ventilation is complete and the building is safe for re-entry.

Appendix IV Label Amendments for Products Containing Paraformaldehyde

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statement must be added to the primary display panel.

POTENTIAL SKIN SENSITIZER

The following statements must be included on the secondary display panel.

Harmful if swallowed.
Extremely hazardous by skin contact. DO NOT get on skin.
Harmful if inhaled.
CORROSIVE to the eye. DO NOT get in eyes.
Potential skin sensitizer.

II) The following must be included in a section entitled **PRECAUTIONS**.

All handlers must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and footwear, chemical-resistant headgear (during overhead application) and a full face respirator. During cleaning of equipment or mixing/loading product a chemical-resistant apron must also be worn.

III) The following must be included in a section entitled **DIRECTIONS FOR USE**.

Fumigant handlers must hold an appropriate pesticide applicator certificate or licence recognized by the provincial/territorial pesticide regulatory agency where the pesticide application is to occur.

Paraformaldehyde fumigation is limited to designated fumigation chambers used exclusively for fumigation of alfalfa leafcutting bee cells and/or nest material.

Warning signs must be placed on fumigation chambers and the surrounding area before fumigation begins. Signs must state: "DANGER – FUMIGATION" and "PARAFORMALDEHYDE" with skull and crossbones symbol, date and time fumigant introduced, and contact information of applicator performing fumigation. Warning signs may not be removed until ventilation is complete and the premise is safe for re-entry.

An eight meter prohibited entry zone must be established extending from, and surrounding, the fumigation chamber. Prohibited entry zone must be clearly identified with cones and cautionary tape. No persons except for properly equipped handlers are permitted within the prohibited entry zone.

Fumigation chambers must be securely locked during all stages of fumigation including: application, fumigation, and ventilation.

Ventilation must achieve a total of 12 air-changes prior to re-entry by unprotected persons.

After transfer of bee cells to the incubator, ventilation of the incubator must continue for 5-7 days to remove residual vapour.

Bags of paraformaldehyde granules not completely used in fumigation operations must be tightly folded and taped shut, placed in single or double plastic bagging, placed in a solid plastic container with snap-top lid, and locked in the fumigation chamber for storage until the next fumigation operation.